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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,036	07/05/2001	Mark Leslie Smythe	4050.001200	3406
23720	7590	03/31/2005	EXAMINER	
WILLIAMS, MORGAN & AMERSON, P.C. 10333 RICHMOND, SUITE 1100 HOUSTON, TX 77042			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1653	
DATE MAILED: 03/31/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/806,036	SMYTHE ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-19,32-35,39,40 and 44-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-19,32-35,39,40 and 44-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/28/05</u> . | 6) <input type="checkbox"/> Other: _____ |

4/2

DETAILED ACTION

Status of the Claims

1. Claims 8-19, 32-35, 39, 40 and 44-52 are pending.

Applicants' amendment filed on January 28, 2005 is acknowledged. Applicants' response has been fully considered. Claims 8, 11, 12, 18, 19, 32 and 33 have been amended, and new claims 44-52. Thus, claims 8-19, 32-35, 39, 40 and 44-52 are examined.

Objection Withdrawn

2. The previous objection to specification regarding the "SEQ ID NO:" for listed amino acid sequences, the term "cat" and Fig. 5 is withdrawn in view of applicant's amendment to the specification, applicant's submission of Fig. 5, and applicant's response at page 19 of the amendment filed January 28, 2005.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 8-19, 32-35, 39 and 40 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's amendment to the claims, and applicant's response at pages 24-27 of the amendment filed January 28, 2005.
4. The previous rejection of claims 8-19, 32-35, 39 and 40 under 35 U.S.C. 112, second paragraph, regarding the claim dependent from a cancelled claim, the term "which may occur spontaneously", "and/or", "A2 is an irreversible substituent, is removed.....upon ring contraction", term "A1 is one or more N-substituents, either reversible or non-reversible, on the peptide backbone", or antecedent basis, is withdrawn in view of applicant's amendment to the claims, and applicant's response at pages 19-24 of the amendment filed January 6, 2005.

Art Unit: 1653

Claim Objection

5. Claim 19 remains objected to because the claim contains recitation of non-elected compounds of formula (a).

In response, applicants indicate the claim has been amended to delete the reference to the non-elected compounds. The response has been considered, however, the argument is not found persuasive because the claim still encompasses cyclohexyl and heterocyclic compounds having nitrogen, oxygen or sulfur in the ring, although the 6-membered phenyl ring has been elected.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 8-19, 32-35, 39, 40 and 46-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21, 23, 30, 31 and 35 of co-pending application 09/787,840. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 8-19, 32-35, 39, 40 and 46-52 in the instant application disclose a method of synthesis of a cyclic peptide or peptidomimetic compound of General Formula I or II, comprising preparing a linear peptide of General Formula III having A1 and A2, wherein A1 is N-substituent on the peptide backbone or

Art Unit: 1653

a chemical moiety that forces a cis conformation, and A2 is a group of atoms comprising a reactive functionality to form an initial large cyclic peptide prior to ring contraction to the desired substituted cyclic peptide, activating the C-terminus to form a large cyclic peptide, subjecting the large cyclic peptide to ring contraction to the desired substituted cyclic peptide, and deprotecting the substituted cyclic peptide. This is obvious variation in view of claims 1-21, 23, 30, 31 and 35 of the co-pending application which disclose a method of synthesis of a linear, cyclic peptide or on-resin cyclization of a peptide molecule, comprising linking a cyclic aromatic or alkyl auxiliary compound to an amine nitrogen atom. Since both sets of claims are directed to a method of synthesis of a cyclic peptide or peptidomimetic compound either in solution or on a solid support, comprising preparing a linear peptide having A1 and A2 by linking a cyclic aromatic or alkyl auxiliary compound to an amine nitrogen atom, and cyclizing the peptide. Therefore, claims 8-19, 32-35, 39, 40 and 46-52 in instant application and claims 1-21, 23, 30, 31 and 35 of the co-pending application are obvious variations of a method of synthesis of a cyclic peptide or peptidomimetic compound either in solution or on a solid support, comprising preparing a linear peptide having A1 and A2, where A1 and A2 are used to facilitate the cyclization reaction.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1653

7. Claims 8-19, 32-35, 39, 40 and 44-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 8-19, 32-35, 39 and 40 are indefinite because of the use of the terms "P is a linear peptide of 1 to 15 monomers" and. The terms cited render the claim indefinite, it is not clear how a peptide, which is polymer, can be only one monomer since a peptide is composed of two, three or many amino acid residues which are linked with a peptide bond (CO-NH) (see Voet et al., Biochemistry page 62-63, Fig. 4-3). Claims 9-19, 34-35, 39, 40 and 44-52 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

In response, applicants indicate that in light of this application disclosure, particularly the definition of "monomer" in the specification (page 22, line 21 to page 23, line 21), one of ordinary skill in the art would have no difficulty in understanding how a peptide can be only one monomer (page 20 of the response).

The response has been considered, however, the argument is not found persuasive because the specification only discloses various compounds such as various amino acid residues as monomers, as indicated in the paragraph above, a peptide by definition has at least one peptide bond (CO-NH) which is formed from condensation of two amino acid residues (peptide units), thus, peptides can be dipeptides, tripeptides, oligopeptides and polypeptides, but not one monomer (see Voet et al., Biochemistry page 62-63, Fig. 4-3).

9. Claim 12 is indefinite because of the use of the term "derivatized". The term cited renders the claim indefinite, it is not clear what chemical procedure is carried out as to

Art Unit: 1653

“derivatized”, and what compound is produced and how different the product is from the parent compound.

In response, applicants indicate that one of ordinary skill in the art would understand that a free functional group provides the ability for synthetic manipulation or derivatization at this functional group. It would be further understood that a wide variety of such reactions is possible, and claim 12 would not be thought unclear by not reciting any particular derivatization.

Applicants respectfully refer to the passage in the specification page 15, line 19 to page 16, line

4. Such derivatization is well-known in the art and is widely used in combinatorial chemistry (see, for example, Ostrech et al., Proc. Natl. Acad. Sci. USA, 91: 11138-42, 1994, Exhibit C; pages 21-22 of the response).

The response has been considered, however, the argument is not found persuasive because the claim does not indicate what derivatization of the functional group is, or what the derivatization is used for, and there are many reactions for derivatization of various A1 or A2, thus it is not clear what metes and bounds for the term “derivatized”.

10. Claim 19 is indefinite because of the use of the term “Z is any group which allows the formation of a covalent carbon-nitrogen bond”. The term cited renders the claim indefinite, it is not clear how A2, which is already attached to peptide (e.g., 6-nitro-2-hydroxylbenzyl), is also a group having Z with a reactive functionality (e.g., CHO) which forms a covalent bond with nitrogen of the peptide.

11. Claims 46 and 48 are indefinite because the structure of A2 does not conform the General Formula III of claim 8. In the Formula III, A2 is attached to the peptide, thus it does not contain the peptide, however, structures of A2 in the claim contain the peptide (R'-NH). Claims 46 and

Art Unit: 1653

48 are also indefinite as to “n” which is not defined. Claim 48 is also indefinite because some structures of A2 (e.g., linear structure) do not conform the 6-membered ring structure of claim 19.

12. Claims 32, 39 and 50 are indefinite as to step d), it is not clear what cyclic peptide is produced if A1 is not a reversible substituent. Claims 39 and 50 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

Conclusion

13. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 09/806,036

Page 8

Art Unit: 1653

Chih-Min Kam, Ph. D.
Patent Examiner

A handwritten signature in black ink, appearing to read 'Chih-Min Kam', with a long horizontal flourish extending to the right.

CHIH-MIN KAM
PATENT EXAMINER

CMK
March 25, 2005